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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,281	10/13/2000	Hyun Kim	GI 5387	9127

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EXAMINER	
WEBER, JON P	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/687,281	KIM ET AL.	
	Examiner	Art Unit	
	Jon P. Weber, Ph.D.	1651	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See attachment*.

3. ☒ Applicant's reply has overcome the following rejection(s): *112, 2nd;102, some 103s*.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See attachment*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *1-7*.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s)_____.

10. ☐ Other: _____

Jon P. Weber, Ph.D.
Primary Examiner
Art Unit: 1651

Status of the Claims

The response with amendments filed 10 September 2002 has been received and but not entered (*vide infra*). Claims 1-7 remain presented for examination.

Claim Rejections - 35 USC § 112

The rejection of claims 1-7 under 112, second paragraph would be withdrawn in view of the proposed amendments in the response of 10 September 2002. However the rejections are adhered to for the reasons of record in view of the non-entry of amendment for the reasons *infra*.

Claim Rejections - 35 USC § 102/103

The rejections under 102 and 103 over Vanis et al. (CZ 283073), Wozney et al. (6,187,742), and Rhee et al. (US 5,752,974) would be withdrawn in view of the proposed amendments inasmuch as none of these references disclose or reasonably suggest hyaluronic acid esters. However the rejections are adhered to for the reasons of record in view of the non-entry of amendment for the reasons *infra*.

Claims 1-5 and 7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al. (US 5,939,974).

It is argued that Valentini disclose implantable compositions, not injectable ones as required by the amended claims. It is urged that the solution referenced in the Office action is only a blending of solutions prior to formation of the scaffold, which is then implanted.

The instant claims are drawn to a composition having functional intended use. It is noted that the scaffolding is formed from the mixed solution by drying from the wet state, preferably by lyophilization without freezing (column 7, lines 22-24). Hence, it is clear that prior to drying, Valentini disclose a solution that meets the limitations of the instant claims. The same preferred hyaluronic acid esters - HYAFF®, the same pore-forming agents, the same tricalcium phosphate and several of the same BMPs, and the same solubilizing organic solvents are explicitly recited as being parts of this composition. There is no indication that the solutions are not injectable, just that it is preferred to dry the solutions to form an implantable porous scaffold.

Applicant's arguments filed 10 September 2002 have been fully considered but they are not persuasive. The rejection is adhered to for the reasons of record and the additional reasons above.

The proposed amendments to the claims would result in withdrawal of several of the relied upon references. This would leave claim 6, without an outstanding rejection, inasmuch as Valentini do not teach OP-1 (aka BMP-7). Hence, a secondary reference, such as Wozney et al. would be needed to encompass a limitation which was properly rejected prior to the proposed amendment. This would constitute new grounds of rejection. It is not proper to initiate new grounds of rejection after final. Accordingly, the amendment is not enterable even though it would have simplified most of the issues.